THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 45

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte CONAN KORNETSKY

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Appeal No. 1995-1990
Application 08/006,691

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HEARD: May 4, 2000

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Before WINTERS, ROBINSON, and ADAMS, Administrative Patent Judges,

ROBINSON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 4, 5, 7, 12-14, 16-19 and 21-22. Claim 15 has been indicated allowable by the examiner in the Office action of May 31, 1994. (Paper No. 31). In the Office action of February 10, 2000, (Paper No. 42), the examiner withdrew the rejections

under 35 U.S.C. § 112, first paragraph. As to claim 9, this was the only remaining rejection of record. Although the examiner has not indicated that claim 9 is allowable, the claim is no longer subject to rejection. Therefore, claims 9 and 15 are not presented in this appeal. Further, claims 23-24 were added by amendment in the paper filed March 31, 1994. (Paper No. 28). The Office action of May 31, 1994 (Paper No. 31) indicates that the examiner approved the entry of this amendment but fails to indicate the status of these two claims. Since claims 23 and 24 depend from allowed claim 15 and are not subject to rejection, we do not regard them as present on appeal.

Claims 1 and 14 are illustrative of the subject matter on appeal and are reproduced below:

1. A method for preventing neuroleptic-induced tardive dyskinesia in a subject, in whom neuroleptic treatment is indicated but who has not received a neuroleptic, comprising:

commencing administration of an effective dose of an opiate receptor antagonist, said antagonist selected from the group consisting of naltrexone, naloxone, nalmefene, and naltrindole, to the subject concurrently with the commencement of administration of a neuroleptic prior to appearance of symptoms of hyperkinesia.

14. A method for treating a genetic hyperkinetic movement disorder in a subject comprising administering to the subject an effective dose of an opiate receptor antagonist, said antagonist selected from the group consisting of naltrexone, naloxone, nalmefene, and naltrindole.

The references relied upon by the examiner are:

Lindenmayer et al. (Lindenmayer), "High-Dose Naloxone in Tardive Dyskinesia," Psychiatry Research, Vol. 26, pp. 19-28 (1988).

Sandyk et al. (Sandyk), "Naloxone Treatment of L-Dopa-induced Dyskinesias in Parkinson's Disease," American Journal of Psychiatry, Vol. 143, No. 1, page 118 (1986)[1].

Grounds of Rejection

Claims[2] 1, 4, and 5 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Lindenmayer.

Claims 7, 12-14, 16-19 and 21-22 stands rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Lindenmayer and Sandyk.

We reverse.

Background

[1] In the Examiner's Answer of September 27, 1994, (Paper No. 34) the examiner has correctly listed the author and title of the reference but has incorrectly listed the journal, volume, page and publication date. The correct publication information is listed at page 3 of the Examiner's Answer of September 1, 1992 (Paper No. 15).

[2] The examiner's statement of the rejection includes claims 1-6. However, Claims 2, 3, and 6 were canceled by applicant in a paper filed March 31, 1994. (Paper No. 28).

The applicant describes the invention at pages 1-3 of the specification, as being directed to a method of modulating hyperkinetic movement disorders in mammals by administering an opiate receptor antagonist to the mammal. Applicant states that the administration of the opiate receptor antagonist can prevent or treat neuroleptic-mediated tardive dyskinesia as well as hyperkinetic movement disorders associated with conditions which are psychogenic, idiopathic, genetic, infectious or drug-induced.

Discussion

The rejections under 35 U.S.C. § 103

Obviousness is a legal conclusion based on the underlying facts. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966); Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1270, 20 USPQ2d 1746, 1750 (Fed. Cir. 1991); Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566-68, 1 USPQ2d 1593, 1595-97 (Fed. Cir. 1987). In considering the issues raised in this appeal we have carefully considered the evidence and reasoning presented by the examiner in support of the rejections of the appealed claims. However, on this record we are constrained to conclude that the examiner has failed to provide those evidentiary facts which would reasonably support a conclusion that the rejected claims would have been obvious within the meaning of 35 U.S.C. § 103.

Claims 1, 4, and 5:

Claims 1, 4, and 5 are directed to a method of preventing neuroleptic induced tardive dyskinesia in a subject comprising commencing the concurrent administration of an opiate receptor antagonist and a neuroleptic, prior to appearance of symptoms of hyperkinesia. The examiner acknowledges that Lindenmayer teaches the administration of the opiate receptor antagonist after symptoms of hyperkinesia appear and at a time after the initial administration of the neuroleptic but argues that the disclosure would have made obvious the administration of the opiate receptor antagonist at any time after neuroleptic treatment including before the time tardive dyskinesia is manifested. (Answer of Sept. 1, 1992, page 4).

We note that the burden is on the examiner to provide a reason, based on the prior art or knowledge generally available in the art, as to why it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297, n.24, 227 USPQ 657, 667, n.24 (Fed. Cir. 1985). On this record, the examiner has provided no factual evidence which would reasonably suggest modifying the disclosure of Lindenmayer in a manner to arrive at a method of preventing neuroleptic induced tardive dyskinesia in a subject by concurrently commencing administration of an opiate receptor antagonist and a neuroleptic prior to the appearance of symptoms of hyperkinesia movement.

Claims 7, 16, 18:

Claims 7, 16, and 18 are directed to methods of preventing hyperkinetic movement disorders wherein a therapeutically effective dose of an opiate receptor antagonist is administered prior to the appearance of symptoms. In rejecting these claims, the examiner relies on Lindenmayer and Sandyk. The examiner acknowledges that neither reference discloses the administration of the opiate receptor antagonist before the movement disorder is manifested, but urges that having disclosed the treatment of such disorders, administration before the appearance of symptoms would have been obvious. (Answer of Sept. 1, 1992, pages 4 and 5). The examiner provides no factual evidence in support of the proposition that once it has been established that a given agent is useful in the treatment of an established condition that this alone would have suggested to those of ordinary skill in the art that the agent would be useful for the prevention of the same condition. Appellant, in rebuttal, offers the declarations of Dr. Sax and Dr. Kornetsky (Paper No. 25) in support of the position that a known treatment does not necessarily give rise to a reasonable expectation of success in the prevention of a given condition. Thus, having weighed the evidence before us, we conclude that the examiner has failed to establish a prima facie case of unpatentability as to claims 7, 16, and 18.

Claims 14, 17, 19:

Claims 14, 17, and 19 are directed to methods of treating a genetic hyperkinetic movement disorder, an idiopathic hyperkinetic movement disorder and a psychogenic hyperkinetic movement disorder, respectively, comprising administering an effective dose of an opiate receptor antagonist selected from the group consisting of naltrexone, naloxone, nalmefene and naltrindole. These claims stand rejected under 35 U.S.C. § 103 as unpatentable over Lindenmayer and Sandyk. The examiner urges that Lindenmayer, which discloses the combined administration of naloxone and a neuroleptic as resulting in an ameliorating effect on tardive dyskinesia, and Sandyk, which discloses naloxone treatment of L-dopa-induced dyskinesia in patients with Parkinson's disease, make obvious the use of such opiate receptor antagonists for the treatment of hyperkinetic movement disorders arising from genetic disorders, idiopathic disorders or psychogenic disorders. (Answer of Sept. 1, 1992, pages 4 and 5 and Answer of Sept. 27, 1994, page 6). Yet, both Lindenmayer and Sandyk are concerned with the treatment of hyperkinetic movement disorders caused by the administration of another drug to the patient and not the treatment of hyperkinetic movement disorders arising from a condition such as those provided for by the claims. In Lindenmayer, the opiate receptor antagonist is administered to treat tardive dyskinesia caused by the administration of a neuroleptic to a patient. In Sandyk, the opiate receptor drug is administered to treat hyperkinetic movement resulting from the administration of L-Dopa to a patient with Parkinson's Disease. The examiner

provides no factual evidence which would suggest that the described results could have reasonably been extended to the treatment of hyperkinetic movement disorders arising from non-drug induced conditions such as those claimed. Absent such evidence, it can not reasonably be concluded that one of ordinary skill in this art would have found it obvious to treat the conditions of the present claims with an opiate receptor antagonist. To the extent that it can be urged that the successes of Lindenmayer and Sandyk would have encouraged those of ordinary skill in the art to try such opiate receptor antagonists in the treatment of other such conditions involving hyperkinetic movement disorders, we note simply that "obvious to try" is not the appropriate legal standard for establishing a prima facie case of obviousness within the meaning of 35 U.S.C. § 103. In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); In re Dow Chem. Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed. Cir. 1985); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380, 231 USPQ 81, 90-91 (Fed. Cir. 1986). Thus, as to claims 14, 17, and 19, the examiner has failed to establish a prima facie case of unpatentability of the claimed subject matter based on the disclosures of Lindenmayer and Sandyk.

Claims 12, 13, 21, and 22:

Claims 12, 13, 21, and 22 are alternatively dependent on claims drawn to "preventing" or "treating" a genetic, idiopathic or psychogenic hyperkinetic movement disorder**.** We have considered the rejection of claims 12, 13, 21, and 22 over Lindenmayer and Sandyk and conclude that the examiner has similarly failed to establish a prima facie case of unpatentability as to the subject matter of these claims whether directed to prevention or treatment for the same reasons discussed above with regard to the independent claims on which they depend.

Conclusion

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). On this record, we find that the examiner has failed to provided the factual evidence which would reasonably establish that the presently claimed methods would have been obvious within the meaning of 35 U.S.C. § 103. In our opinion, Lindenmayer and Sandyk, as discussed by the examiner, would not have made obvious the use of the opiate receptor antagonists required by the claims for the treatment or prevention of neuroleptic induced tardive dyskinesia or hyperkinetic movement disorders arising from genetic, idiopathic or psychogenic conditions. Where the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d

1596, 1598 (Fed. Cir.1988). Therefore the rejections of claims under 35 U.S.C. § 103 over Lindenmayer alone, or Lindenmayer and Sandyk are reversed.

Summary

To summarize, the decision of the examiner to reject claims 1, 4, 5, 7, 12-14, 16-19 and 21-22 under 35 U.S.C. § 103 is reversed.

REVERSED

Sherman D. Winters Administrative Patent Judge	)
Douglas W. Robinson Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Donald E. Adams Administrative Patent Judge	)

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